UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	)	Judge Patti B. Saris
	)	Chief Magistrate Judge Marianne B. Bowler

WRITTEN TUTORIAL OF
DR. MEREDITH ROSENTHAL

[REDACTED VERSION]

Biographical Sketch

Before I turn to substance let me tell you a little about my background. I am currently an Assistant Professor of Health Economics and Policy at Harvard School of Public Health.[1] At the School of Public Health, I teach Health Economics to Masters students and spend the remainder of my time working on grant-funded research projects.

I received a Ph.D. in the Economics Track of the Health Policy program at Harvard. My training at Harvard covered both economic theory and empirical methods and the substantive areas of public health and health policy.

A major area of my research has been the economics of the pharmaceutical industry. With several of my colleagues at Harvard and Professor Berndt, I examined trends in direct-to-consumer advertising of prescription drugs and its impact on consumer demand. We published several peer-reviewed papers and reports on those findings over the past three years. I have also been interested in pharmacy benefit design, both from the perspective of Medicare reform and private-sector efforts to reduce pharmaceutical spending or improve the value of dollars spent. In this line of research, I am currently working on an evaluation of tiered formularies in managed care to see what impact they have on spending and use of pharmaceuticals.

The other major area of my research that is relevant to this case is the economics of incentives. In particular, I have examined the financial incentives created by different physician payment systems and how they affect treatment choices and other behavior.

From 1997 to the present, I have been a referee for the *Journal Of Health Economics, Health Affairs,* and *Health Services Research*, among others, all of which feature frequent articles on the pharmaceutical industry and pharmacy benefit management.

In connection with this case, I have spent approximately 100 hours analyzing the distribution of pharmaceutical products, the role of AWP generally in drug pricing/reimbursement, and the incentives that might give rise to the specific allegations of abuse of AWP-based reimbursements. I first looked to the scientific literature and industry press for evidence on the economic relationships in the market and how payments flow through the distribution chain. I then reviewed contracts between PBMs and third-party payors and health and welfare funds, PBM contracts and pharmacies, third-party payors and physicians, and PBMs and manufacturers. I also examined discovery materials relating to the use of AWP for reimbursement and for strategic purposes. Finally, I reviewed a large number of data analyses that were produced in the case using manufacturer invoice and insurance claims data to illuminate the interrelationships among actual sales prices, third-party reimbursement, and list prices over time for the drugs named in the complaint.

[1] CV of Meredith Rosenthal attached as Exhibit 1.

Preliminary Point

It is my understanding that the operative complaint and the motion for class certification seek to have this Court treat on a collective basis the claims of endpayors (including third-party payors and consumers) that they have over-reimbursed or overpaid for 132 specified "AWPIDs" (a term of art used by the plaintiffs to describe those drugs for which the AWP was alleged to have been inflated resulting in actionable conduct) manufactured and/or distributed by five designated drug manufacturer groups (AstraZeneca, BMS, GSK, J&J, and Schering Plough), and that the recovery is sought for both private co-payments made under the Medicare Part B system and for private payments based on the AWP for pharmacy (including mail order) distributed AWPIDs.

For the purposes of this tutorial, the critical observation I make is that almost universally the drugs at issue in this case are reimbursed or paid for by endpayors using as the reimbursement benchmark the published AWP (or to a lesser extent the related published WAC) regardless of differences in therapeutic usage and distribution patterns. Put differently, when all is said and done – and despite differences in insurance plans, formularies, mode of administration, brands versus generics, and negotiations – endpayors most frequently reimburse or pay pharmacies and providers for outpatient drugs using a system that relies upon the administrative efficiency and general accuracy and reasonableness of reimbursing based on manufacturers' published AWPs. The commonality of these systems and the overwhelming use of AWP give rise to common issues from an economist's viewpoint.

In their motion requesting a tutorial, defendants claim that pricing and reimbursement is complex and presents many individual issues. The pharmaceutical industry may be complex, but it is no more complex than many other industries where experts and economists are able to isolate the impact of a common practice.

Despite differences in the types of health plans in the proposed class and differences in the terms of their contracts with PBMs or providers, the proposed class is bound together by the use of AWP. If AWP for a particular AWPID has been manipulated or artificially raised and given the use of AWP as a reimbursement benchmark for most drugs in the United States pharmaceutical industry, that manipulation has an impact that can be observed and measured on a class-wide basis.

Small Number of Drugs at Issue

Before I turn to the workings of the pharmaceutical industry it may be useful to put some perspective on the use of AWP in the pharmaceutical industry.

There are approximately 65,000 different prescription drugs in the United States market. The use of AWP as a pricing mechanism for the vast majority of these drugs is not at

issue in the AMCC or in this motion.[2] Plaintiffs instead claim that with respect to 132 of the drugs manufactured by the five fast track defendants (a subset of all drugs manufactured by these companies),[3] the use of AWP as an industry standard was exploited by defendants and other major players in the pharmacy distribution chain to the disadvantage of those who paid for those drugs: third-party payors and individuals making coinsurance payments for these drugs. As I see my task, it is to try and serve as an aid to the Court in understanding how the drugs at issue in this motion are distributed and paid for by members of the proposed classes, and to discuss how such payment is affected by AWP to aid the Court in deciding whether this case can proceed as a class action.

I am going to use as a tool from time to time the documents defendants created to explain the use of AWP. Where defendants, or other industry participants have described key facts in documents, their own words might be as persuasive as any exhibit or graphic created by an expert.

I am submitting this tutorial in both video and written format to the Court and to Professor Berndt. The written version includes exhibits that I do not refer to in the video version but maybe more appropriate in the written version which is also a bit more detailed.

Medicare Part B

Let me start with a description of the Medicare Part B Program. I start there because Medicare's adoption of AWP for reimbursement is prescribed by regulation and statute. I also understand that the Court may have more questions on the oral or "self-administration" side of the case. However, I think it may aid the Court in understanding AWP and its use to briefly walk through Medicare Part B and then spend more time on the pharmacy channel/PBM side.

Currently (and during the class period, with only some relatively small variations), Medicare Part B generally covers drugs that are "incident to" a physician's service, durable medical equipment (DME) drugs, and drugs specifically covered by statute (for example, oral immunosuppressive drugs). Drugs that fall under the category of "incident to a physician's service" include drugs that cannot be self-administered such as injectable and intravenous agents for oncology, rheumatoid arthritis, and nausea.

Currently, with respect to the five fast-track defendants, the following drugs fit this category:

[2] The fact that for 99% of prescription drugs AWP works and is not being challenged highlights why AWP is an accepted pricing benchmark and further highlights why there was no widespread knowledge of the abuse alleged in the AMCC.

[3] Table 1A identifies these drugs, attached as Exhibit 2.

Drug Name

Alkeran
Blenoxane
Cytoxan
Etopophos
Floxin
Kytril
Levaquin
Navelbine
Paraplatin
Procrit
Remicade
Rubex
Taxol
Vepesid
Zofran
Zoladex
Zovirax

To get a sense of what these Medicare Part B drugs are like, let me describe the leading drugs in this category in the mid-1990s (all of which continue to be important therapies).

Part B Drug Rank in 1995 Expenditures	Drug Is Used For
1. Lupron	Prostate Cancer
2. Albuterol	Asthma
3. Taxol	Breast, ovary and lung cancer

Lupron and Taxol are agents that are used to treat some of the most prevalent cancers among the Medicare population. Albuterol is a very common asthma drug; Medicare only covers it when it is administered by nebulizer (a machine that administers a course of treatment through a mask). Patients with moderate or severe asthma, emphysema, or chronic obstructive pulmonary disease, a serious respiratory condition, are administered such treatment to relieve bronchospasms. Thus Albuterol accounts for a big share of Medicare Part B expenditures in part because the chronically ill people who require the medication use it repeatedly.

Who Is in the Part B Class

Let me pause a moment to describe who are members of the Part B class.

For a Medicare Part B covered drug, 80% of the cost is paid for by the federal government, 20% is paid for by whoever is responsible for the co-payment.

An individual Medicare recipient may have supplemental insurance coverage and whoever provides that coverage will then pay the coinsurance. These third-party payors

are members of the Part B class. There are more than four million Medicare enrollees who do not have supplemental insurance coverage and must pay their own coinsurance for Part B covered drugs.[4] For those persons who have some form of coverage for the Medicare Part B copayment, features of that coverage (*e.g.*, deductibles, caps, etc.) may well result in the individual becoming obligated to pay some portion of the co-insurance on a co-insurance basis.

Also, it should not be forgotten that in many cases, a cancer patient, for example, will take more than one Part B covered drug (*e.g.*, a chemotherapeutic agent and an anti-nausea drug to counteract the former's side effects); if both drugs are subject to unlawful AWP inflation, then the impact of an artificially inflated AWP is magnified on such a patient.

During The Class Period, AWP Is the Part B Pricing Benchmark

The Medicare program was established in 1965 as an amendment to the Social Security Program. Medicare provides health insurance to persons age 65 and older, to qualifying persons under 65 with disabilities, and to persons of any age suffering from permanent kidney failure. Medicare is the nation's largest health insurance program, covering over 39 million people in 2003. It is composed of three parts, a Hospital Insurance Program (Part A), the Supplementary Medical Insurance Program (Part B), and a managed care program (Part C, also called "Medicare Plus Choice" or "Medicare Advantage") that offers enrollees the opportunity to join a commercial health plan instead of receiving coverage through Parts A and B. Part B, which primarily covers physician services, is optional and has a monthly premium requirement. Most Medicare eligibles choose to enroll in Part B and either pay the premium themselves or have it covered by Medicaid or private supplemental coverage. Medicare coverage is subject to substantial deductibles and a 20 percent coinsurance requirement.

When Medicare was designed in 1965, it was modeled on the major medical plans then popular in the private sector, which were primarily intended to cover catastrophic health care costs with substantial cost sharing at the front end (*i.e.*, deductibles and coinsurance). In addition, Medicare, like most employer-sponsored plans in 1965, did not offer routine coverage for outpatient prescription drugs. A small group of specialty drugs, however, was and is covered under Medicare Part B. Typically these drugs are administered by physicians in the office setting or in hospital outpatient departments, but some self-administered drugs are also covered.[5]

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[4] *See* Distribution of Supplementary Insurance for the Medicare population, attached hereto as Exhibit 3.

[5] Currently, those drugs that "are not usually self-administered by the patient" are covered under Medicare Part B. Until December 2000, when Congress amended the statutory standard, covered drugs included "those that cannot be self-administered." *See* §112 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act ("BIPA"). In addition, the Centers for Medicare and Medicaid Services ("CMS") has issued Program Memoranda with guidance for how the new BIPA standard should be implemented (PM AB 02-139).

Reimbursement for prescription drugs under Part B in the Medicare program has been based on the Average Wholesale Price ("AWP")[6,7] reported by drug manufacturers and published in the standard directories (Red Book, First Databank (Blue Book) and Medispan). While the precise formula for AWP-based reimbursement has changed over time, reliance on AWP has been a constant.

More specifically, the Social Security Act Amendments of 1965 (P.L. 89-97) explicitly links reimbursement to cost as follows:

> "The amount paid to any provider of services with respect to services for which payment may be made … shall … be the reasonable cost of such services…"[8]

The original intent of Congress was to pay a reasonable amount to providers for the care of Medicare patients.[9] In a 1995 article, Robert Ball, who served as commissioner of Social Security under Presidents Kennedy, Johnson, and Nixon, provides an insider's insights concerning the intentions of Medicare legislators.[10] In connection with drugs administered in hospitals, he states that:

> "By and large, our posture at the beginning was one of paying full costs and not intervening very much in how hospitals, at least the better ones, conduct their business … We believed in paying fully. We opposed shifting costs to other payers, and we avoided discounts beyond what our contractors might have secured for their own insured persons … We were willing to allow a ***somewhat*** higher reimbursement rate for nursing the elderly..." (Emphasis added.)

In connection with drugs administered in a physician's office, he states that:

> "Reimbursement was to be a 'reasonable' charge determined by the customary charges of the particular physician and the prevailing charges in the locality for similar services."

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[6] "Apparently from the beginning of the program, Medicare has based payment for drugs on published 'average wholesale price' (AWP). AWP is used throughout public and private insurance programs as the basis for drug reimbursement, both for drugs administered in physician offices and for drugs dispensed by pharmacies. The amount of reimbursement varies from plan to plan and setting to setting, but it is almost always expressed as a percentage of AWP." American Society of Clinical Oncology (ASCO), *Reform of the Medicare Payment Methods for Cancer Chemotherapy,* May 2001, p. 5.

[7] Medicare currently pays 95 percent of AWP for drugs administered in a physician's office.

[8] In connection with hospital inpatient expenses, *see* § 1813 (b) of the Social Security Act Amendments of 1965 ("Medicare"). In connection to supplementary benefits of the Act, it is stated in Part B § 1833 (a) that "… there shall be paid ... [for] each individual who is covered … amounts equal to … 80 percent of reasonable charges…"

[9] Beck, D. F., 1984, *Principles of Reimbursement in Health Care*, Aspen Publication, Rockville, MD, p. 3.

[10] Ball, R.M., 1995, *What Medicare's Architects Had in Mind*, HEALTH AFFAIRS, 14(4), pp. 62-72. The specific quotes that follow in this paragraph are found on pp. 68-69.

Prior to January 1, 1998, Medicare carriers were to determine the allowed amount for a covered drug based on the lower of the Estimated Acquisition Cost ("EAC") or 100% of the national AWP for that drug. The EAC was to be determined based on a survey of actual invoice prices paid for the drug and thus designed to represent the actual cost (or "usual and customary charges") of drugs for direct purchasers (the providers, in the case of Medicare Part B).

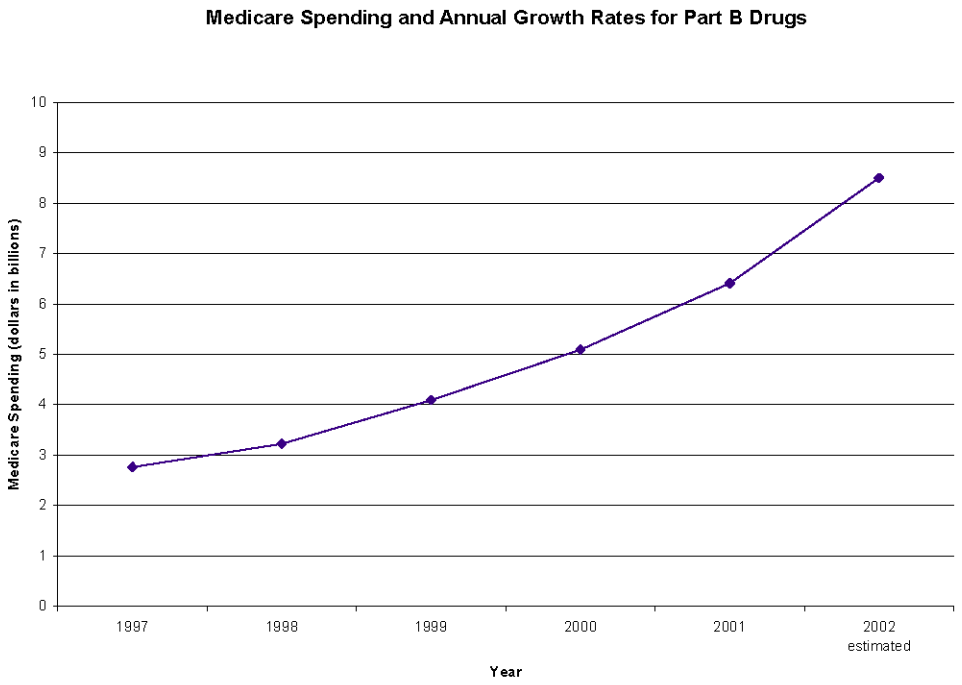
Historically, however, Medicare carriers have not conducted such surveys and have based reimbursement on AWP.[11] Furthermore, on January 1, 1998, 42 C.F.R. § 405.517 was amended so that the allowed amount would be based on the lower of the billed charge on the Medicare claim form or 95% of AWP. In practice, this has meant that the majority of reimbursement has been undertaken using the AWP.

As with other sectors, there has been rapid growth in Medicare Part B drug expenditures. Analysis of the sources of this growth reveals that only a few of the approximately 450 covered drugs account for most of the spending. As noted earlier, Medicare drug expenditures in 1998 were about $3.3 billion and this amount grew to more than $8.4 billion by 2002.[12] During the same period (1998 to 2002), Medicare enrollment grew only 1.4 percent per year while drug spending grew an average of 27 percent per year. The vast majority (77%) of the Medicare Part B drug expense is paid to oncologists and urologists. Oncologists-based drug expenditures grew from 1.2 billion in 1998 to $3.8 billion in 2002 with the spending growth from 2001 to 2002 at 41 percent. The spending on drugs under Medicare Part B is highly concentrated with seven of the approximately 450 drugs accounting for approximately 48 percent of the spending ($4.0 billion out of $8.4 billion). Nineteen drugs accounted for 75 percent of the total drug expenditures and 33 drugs accounted for 86 percent of the total. Both drug product price increases at the manufacturer level and increases in utilization appear to have been the major contributors to growth in drug expenditures for the Medicare Part B program.[13]

[11] *See* "Excessive Medicare Payments for Prescription Drugs," Office of Inspector General, Department of Health and Human Services, December 1997, OEI-03-97-00290, p. i.

[12] Department of Health and Human Services, Center for Medicare and Medicaid Services, "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule," Federal Register, Aug. 20, 2003, 50428-52.

[13] *Medicare and Medicaid Drug Pricing: Strategy to Determine Market Prices*, p. 8-9.



Source: MedPAC Report to the Congress, "Variation and Innovation in Medicare," June 2003, p. 154.

Incentives Created by Part B AWP Reimbursement

If physicians' profits are a function of quantities administered and the spread between the AWP and the transaction price, manufacturers' profits are a function of quantities administered and the margin between transaction prices and costs. Thus, a manufacturers' rational economic response in this setting is to set transaction prices to be profit maximizing and set AWPs as high as possible to increase physician profits and thereby the demand for their drug.

In the marketplace for Part B coverage, the use of AWP as a fixed reimbursement amount can provide incentives to abuse the AWP-based reimbursement structure through marketing of the spread to physicians in order to influence physician usage for a particular drug.

An example of how the AWP-based reimbursement system can be subject to abuse can be shown through some examples of how drug companies have actually conducted business in the AWP-based system in the Part B context.

The first document I refer to concerns the Part B covered drug Vepesid which is a drug manufactured by Bristol Myers Squibb ("BMS"). [redacted]

[redacted][14] [redacted]

Another example of the economics incentives created by the spread is contained in the BMS document entitled, "Taxane Economics" [redacted][15]

A document produced by AstraZeneca has a blunt reference to this incentive: [redacted][16]

What these documents show, and there are many others I could display, is the recognition by drug companies of the ability to increase Part B market share using the disparity between AWP and acquisition cost.

There Is Little or No Variation in the Reliance on AWP for Part B Covered Drug Reimbursement

Defendants' motion seeking a tutorial lists a host of factors claimed to add complexity to drug reimbursement such that no or few common issues exist. For example, defendants claim that, "some transactions have nothing to do with AWP," or that "some drugs are sold to physicians, some are not."

In the Part B context in particular, in my opinion, none of this matters — virtually all transactions are based on AWP by statute. If AWP has been artificially inflated, standard econometric techniques and analysis can be employed to measure that inflation on a class-wide basis.

Private Third-Party Payor Reimbursement for Physician-Administered Drugs

Let me move out of the Part B context but stay with physician-administered drugs. There are physician-administered drugs provided to patients that are not covered by Part B. They could be the same drug that is covered by Part B but the patient is not covered by Medicare. Or, the drug could be an administered drug not covered by Medicare at all.

Physician-administered drugs are often grouped with a class of medications known as specialty drugs. The specialty drug category typically includes injectable drugs, infusible drugs, biotechnology drugs, and other medications administered in a physician's office. One of the major differences between Part B drugs and the types of medications

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[14] BMS AWP at 0011221, attached as Exhibit 4.

[15] BMS AWP 000157426, attached hereto as Exhibit 5. *See also* BMS 000157428 [redacted] attached as Exhibit 6.

[16] AZ 0021838, attached hereto as Exhibit 7; *see also* AZ 0037018-19 referring to [redacted], attached as Exhibit 8.

classified as specialty drugs in the private market is that a much greater percentage of private injectables are self-administered and delivered by pharmacies directly to the patient's home. Specialty drugs treat life-threatening and chronic conditions such as cancer, HIV/AIDS, hemophilia, hepatitis C, multiple sclerosis, rheumatoid arthritis, and anemia. Medications for these conditions are distinguished by their high cost ($5,000 to $250,000 per patient per year).

IMS Health, a large pharmaceutical market research and consulting firm, estimates that purchasers spent $19 billion on specialty drugs in 2001, an increase of 24 percent from 2000. These drugs represent about 11 percent of the United States pharmaceutical market and are its fastest growing sector. One analyst estimates that the use of injectables alone has doubled over the last five years.

In this circumstance, individuals with private health insurance are also covered for prescription drugs administered by a clinician under their medical benefit. AWP is the pricing standard used in this context as well. The Medicare Payment Advisory Commission (MedPAC) contracted with Dyckman & Associates in 2002 to conduct a survey of private health plans regarding their payments for physician-administered drugs. ***The surveyed plans had a combined commercial enrollment of 45 million lives***. That survey found that **"*all of the plans*"** use a percentage of AWP as a formula to reimburse physicians for these drugs.[17] The study found "that most plans use a pricing formula that is in the range of 90% to 100% AWP, with the average at 98% of AWP." Therefore, the incentives that I described above associated with Part B reimbursement of physician-administered drugs are replicated in the private insurance market, and the essential role of AWP as a reimbursement benchmark is also present in that market.

Role of Publishers

Before I move to the pharmacy channel or PBM part of the case, let me explain how AWP is transmitted to the marketplace.

In all instances the AWP is established by the manufacturers either directly or indirectly. In the direct approach, a manufacturer sends an AWP or suggested AWP to a publisher. An example is found in the following document, which is a transmittal of AWP information to First Data Bank.[18] Another example is found in a document from Centocor, part of the Johnson & Johnson Group, transmitting an AWP for Remicade.[19]

Those AWPs are then published by the publisher, either with modification or without, but the publisher always seeks verification from the company prior to publishing an AWP.

[17] Health Plan Payment for Physician-Administered Drugs, a study conducted by Dyckman & Associates for the Medicare Payment Advisory Commission, August 2003, p. 3, attached as Exhibit 14.

[18] FDB-AWP 04045, attached hereto as Exhibit 9.

[19] WKH 01029, attached hereto as Exhibit 10.

There is regular communication back and forth between drug companies and the publishers regarding AWP.[20]

Other companies, [redacted]

Either by submission of AWP or a number from which AWP is derived, all manufacturers control AWP. And as we will see later, all contracts or transactions at issue in this motion use these published AWPs as a pricing benchmark.

Potential For Lack Of Transparency

Because the AWP-based system of pharmaceutical reimbursement is based on the voluntary and fair reporting of AWPs by drug makers, the system has the potential for – and as claimed by the AMCC occasionally actualized – abuse and lack of transparency.

The actual acquisition cost ("AAC") of a drug is known by each drug manufacturer, but is not published or made public.

The AAC is the cost to the provider, or doctor in the Part B context, and the PBM or retailer in non-Part B context.

Some drug manufacturers may have a variety of terms for specific discounts that are based on class of trade, volume of purchase, market share movement, preferred formulary status, terms of payment, and other criteria.

The average sales price ("ASP") is meant to be the net price after all forms of discount, rebate, purchasing allowances or any other forms of economic consideration have been taken into account.

Because drug manufacturers consider the discounts proprietary and confidential, the relationship of AAC or ASP to either AWP or WAC is not predictable from public data sources in general, or for specific classes of trade. It is not known to the health plans.

In the Medicare Part B context, in appears that the established or perceived abuse was sufficiently rampant that last year Congress passed the Medicare Modernization Act of 2003. Among other things, Congress changed the basis of reimbursement for Medicare Part B drugs; to simplify, Congress required the phasing in of a new, Average Sales Price or ASP-based, system to replace the AWP system.

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[20] *See, e.g.*, MDL CEN 00004025, attached hereto as Exhibit 11.

[21] BMS AWP 0011250, attached hereto as Exhibit 12.

Once implemented, Medicare Part B drug and biological reimbursements will be based on a mathematically calculated ASP plus 6%.

PBM Side of the Case

Now I will turn to the "PBM side of the case," or one might call it the pharmacy side of the case because now from a distribution standpoint, we are examining oral drugs sold by pharmacies to consumers, with PBMs playing a role in that process.

Before I describe the role of PBMs, let me pause and describe the members of the proposed class on the PBM side of the case.

The class here consists of third-party payors, and individuals who made a coinsurance payment for one of the drugs manufactured by the fast-track defendants.

Third-party payors are managed care companies and other health insurers that choose to delegate responsibility for managing their pharmacy benefit to a PBM.

Health and welfare plans, are self-insured entities that provide health benefits, including pharmacy benefits, for members of a particular union (*e.g.*, the Teamsters). Other self-insured entities such as large employers like GE will also be class members.

As I will describe later, each of these entities in the proposed class has a relationship with a PBM. Among other aspects of the relationship, one that is critical here, is that relationship almost always has contract terms that utilize AWP as a pricing benchmark, but more on that later when we examine the contracts between drug manufacturers and PBMs, and those between PBMs and their own clients.[22]

The PBMs

Let me start with a description of the PBMs.

The 1990s was a decade of particularly strong growth of the PBM industry as the number of people enrolled in pharmacy benefit plans ballooned from 26% of the U.S. population to 70% in 2000. At the same time, the advent of managed care introduced the concept of tightly controlling health-care utilization, and the use of pharmaceuticals was not spared. PBMs increasingly sought to control which drugs were consumed by their members, narrowing the lists of drugs that were covered by their benefit plans (lists known as formularies) and more tightly managing them in order to concentrate prescription volume with specific products, thus generating higher manufacturer rebates. These increases in membership and control over pharmaceutical utilization led to an increase in the influence of the PBM industry, which did not go unnoticed by pharmaceutical manufacturers. Increasingly, manufacturers were paying large discounts or rebates to the

[22] In this case, the proposed class by definition includes only payors that reference AWP in their contracts.

PBMs, based on the volume of specific drugs that each PBM's members consumed. Worried that this trend would crimp their profits, in the early 1990s, many pharmaceutical manufacturers acquired PBMs. Most, however, reversed course and sold their PBMs when it became clear that the Federal Trade Commission (FTC) was not going to allow unfettered drug company control of PBM formularies.

PBM Acquisitions by Drug Companies

Drug Company	PBM	Year Acquired	Current Status
Merck & Co.	Medco Containment Services	1993	Medco spun off 2002
SmithKline Beecham	Diversified Pharmaceutical Services	1994	DPS sold to Express Scripts in 1999
Eli Lilly and Co.	PCS Health Systems	1994	PCS sold to Rite Aid in 1999 (Rite Aid sold PCS to Advance Paradigm in 2000)

Pharmacies also felt the growing influence of the PBMs. Already thin profit margins on prescription drugs were made even thinner as PBMs ratcheted down pharmacy reimbursement with their market clout — any pharmacy that refused to discount adequately was simply cut out of the PBMs' pharmacy networks (that is, pharmacies its members could use). In defense, several national drug-store chains either acquired or started their own PBMs. (*See* figure below.)

Pharmacy-Owned PBMs

Retail Pharmacy Chain	PBM	Membership (millions)
Rite Aid	PCS Health Systems[23]	48
Eckerd	Eckerd Health Services	16
CVS	PharmaCare	12
Albertson's and Long Drug Stores	RxAmerica[24]	6
ShopKo	ProVantage Health Services[25]	5

[23] Acquired by Advance PCS in 2000.

[24] Joint venture between Albertson's and Long Drug Stores.

[25] Acquired by Merck-Medco in 2000.

Walgreens	Walgreens Health Initiatives	5
Kroger	Kroger Managed Prescription Drug Program	N/A

Today, the ever-increasing importance of pharmaceuticals (and the disproportionate cost growth relative to other health care services) is fueling demand for PBM services focused on cost containment. One of the most important of these services is the PBMs' mail-order pharmacies. These pharmacies deliver pharmaceuticals in three-month supplies to chronic users, and in the process, lower the cost to the payor (mail-order pharmacies are larger, more efficient and thus often less expensive than a corner drug store) and the plan member (who is usually charged only one or two copays every three months).

PBM Market Share

Top PBMs by Membership

PBM	Membership (millions)
AdvancePCS	75
Merck-Medco Managed Care	65
Express Scripts	48
WellPoint Pharmacy Management	30
Caremark Rx	23
MedImpact Healthcare Systems[26]	20
Eckerd Health Services	16
Aetna Pharmacy Management	14
PharmaCare (CVS)	12
First Health Services[17]	12
Pharmacy Services Group	11
MIM Health Plans	9
National Prescription Administrators[27]	8
Consultec[17]	7
RxPrime (Cigna)	6
RxAmerica (JV betw. Albertson's and Long Drug Stores)	6
Prime Therapeutics[17]	5
Prescription Solutions (Pacificare)	5
Anthem Prescription Management	5
Walgreens Health Initiatives	5
Managed Pharmacy Benefits (Cardinal Health)	3
Systemed[28]	2

[26] Primarily a provider of prescription claims-processing services.

[27] Acquisition by Express Scripts pending.

[28] Subsidiary of Merck-Medco focusing on small plans.

PBM	Membership (millions)
RESTAT	2
The Inteq Group	2
Health Resources	2
Total Reported	**392**
ACTUAL Total PBM Membership	**180**

A Transaction

The easiest way to describe how the PBMs make money and how the payment system works is to walk through the process of filling a prescription and everything that goes on behind the scenes (at the PBM), as that prescription gets filled, billed and paid for. Every arrow in the flow chart represents an exchange of money between the parties to this process.[29]

The list of activities and the related revenue stream below correlates to the numbers in Exhibit 13. I start with a plan member walking into a drug store to purchase a prescription drug.

(1) A plan member walks into a drug store with a prescription (or perhaps submits a prescription via fax to a mail-order pharmacy). The pharmacy clerk takes the prescription and insurance card from the member, swipes the insurance card or enters the number on the card into a computer system linked to the PBM, verifies that this person does indeed have insurance coverage for this prescription and checks to see what copay is owed. Assuming the customer is covered and can afford the copay, the prescription is filled, and the clerk enters into the computer system the information necessary to create an insurance claim. The customer walks out with a filled prescription.

(2) The insurance claim is then routed to the PBM, typically electronically and on a real-time basis. Of course, some pharmacies still process insurance claims the old fashioned way, doing them in a batch at the end of a day or week and perhaps even using paper forms and fax machines.

3) In our example, once every two weeks (though in reality it could occur less or more frequently), the PBM will turn to its clients (the plan sponsor or payor, be it a health insurer or self-funded corporation) and collect from them the per-prescription administrative fees ($0.30-0.40) due them for the number of prescriptions filled by their plan members over the previous two weeks, a per-prescription "dispensing fee" that is paid to the pharmacies as compensation for the service they provide in filling a prescription (around $2.50 on average) and the agreed cost of the prescriptions so that the PBM can reimburse the pharmacies. The cost is defined by the contract between the plan and the PBM.

[29] The PBM Money Flow Chart, attached as Exhibit 13.

(4) Eventually (perhaps two weeks later or four weeks after the prescription was filled), the PBM will pay the pharmacies the cost of the pharmaceutical and the dispensing fees for all of the prescriptions that they have filled. The amount paid to the pharmacies for the pharmaceutical itself is almost always the average wholesale price (AWP) minus a prenegotiated discount, which is about 15% on branded pharmaceuticals and 13%-25% on generics. However, the amount collected from the client (payor) for the pharmaceutical is typically slightly more than the amount paid to the pharmacy, a discount of say 13% off of AWP. This "spread," which is a function of AWP, is another source of revenue for the PBMs.

Thus for the health plans, nearly every time a member buys a drug, AWP is implicated.

How Does AWP Come Into Play in the PBM System

My study of the literature and defendants' own documents reveal one fact that I suggest to the Court is key to your consideration of this motion — AWP is the overwhelming basis for reimbursement of brand-name drugs — both in the PBM context and the physician-administered context discussed previously.

A variety of evidentiary materials demonstrate that private sector third-party payors negotiate reimbursement rates for oral pharmaceuticals based upon AWP. For oral prescription drugs, it is widely known that PBMs and health insurers reimburse retailers based on AWP. A recent policy brief by the George Washington University noted, "PBMs base their pharmacy reimbursements on the AWP for brand-name drugs."[30] A report by the FTC/DOJ also documented the use of AWP as a benchmark for PBM reimbursements,[31] and outlined how this works in practice at both the PBM-to-pharmacy level and PBM-to-health plan level:

> To perform its services, a PBM enters contracts with healthcare plans, retail pharmacies, and drug manufacturers. When a PBM establishes retail networks, it contracts with retail pharmacies on reimbursement amounts for drugs dispensed by the pharmacy. For a given drug, the price that the PBM will reimburse a retail pharmacy is stated as a discount from a measure of wholesale price plus a dispensing fee for the pharmacy. For brand-name drugs, the "average wholesale price" (AWP) as stated by the manufacturer is used as a basis for the discount, so the price formula would be, for example, "AWP – 10% + $2.00." For generic drugs, the average price used is the "maximum allowable cost" (MAC) as specified by the PBM, so the formula might be "MAC – 10% + $2.00.")

[30] Gencarelli, Dawn, *Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism*, HHPF Issue Brief, No. 775/June 7, George Washington University, 2002 at p. 11.

[31] A report by the Federal Trade Commission and the Department of Justice, July 2004, at Chapter 7, pages 13-14.

> The PBM's contract with a plan sponsor covers the amount that the plan sponsor will pay the retail pharmacy per prescription of each drug, as well as separate charges for the variety of PBM services that the plan sponsor may utilize. The PBM's charge to the plan sponsor per script is similar in form to the retail pharmacy contract. For brand-name drugs, it is a discount off AWP plus an administration charge per script, *e.g.*, "AWP – 5% + $0.10." For generic drugs, the charge has the same form except the discount will be from the MAC as specified by the PBM.[32]

AWP Is Reflected in Defendants' Documents

In coming to conclusions concerning the persuasiveness of AWP, I have also relied upon defendants' own documents, which refer repeatedly to AWP as the "industry standard."

For example, a document produced by a PBM on AWP describes AWP as follows:

- "AWP is the average of the prices charged by the national drug wholesalers."
- "AWP is the most common reimbursement mechanism used in the marketplace."[33]

Another document produced by BMS is from a presentation made by AdvancePCS, one of the major PBMs, which describes AWP as:

[redacted][34]

In describing "how drugs are reimbursed, a BMS document observes that [redacted][35] Elsewhere, BMS describes that: [redacted]

Again, despite the alleged complexity of the distribution chain when it comes to AWP, defendants refer to its use as the standard.

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[32] As we discuss elsewhere, MAC is not always utilized and many generic transactions are AWP based.

[33] BMS AWP 000100778, attached as Exhibit 15.

[34] BMS AWP 000125509, attached hereto as Exhibit 16 (emphasis added).

[35] BMS AWP 000101009, attached hereto as Exhibit 17(emphasis added).

[36] BMS AWP 000101010, attached hereto as Exhibit 18; *see also* BMS AWP 000192749 — [redacted] attached hereto as Exhibit 19.

Contracts Use AWP

Another way to see the widespread and common use of AWP in the oral or PBM part of the case and to understand why it is called the "industry standard" is to examine actual contracts. There are two levels of contracts to examine here. First, there are contracts with PBMs and their health plan clients. Second, there are contracts between the pharmacies and PBMs. Virtually all of those contracts use AWP as the payment benchmark. Let's look first at the contracts between PBMs and health plans.

The contracts between PBMs and health plans uniformly use AWP as a reference for both brand name drugs,[37] as well as for generics.

Similar uniform language regarding the use of AWP is contained in the contracts between PBMs and pharmacies.[38]

It is also worth noting that there is not a lot of variation to the amount of the stated discount in these contracts. Typically, it's AWP-15% for brand name drugs.

Again, documents produced in this case confirm the uniform nature of AWP as a basis for reimbursement. [redacted]

There Is Widespread Commonality Created by the Use of AWP

The pervasiveness and uniform use of AWP in the distribution chain is nicely demonstrated by some flow charts created by one of the PBMs for a presentation apparently made to BMS. [redacted][43]

Reimbursement for Generic Self-Administered Drugs

Let me say a few words about reimbursement for generic drugs in the self-administered (retail) side of the case. Generic drugs are reimbursed based on a different formula. In

[37] Exhibit 20 contains samples of contract language between each major PBM and health plan clients. Typical relevant contract language with a health plan states that the cost to the health plan is "AWP less 13%." *See* Exhibit 20 at p. 1.

[38] Exhibit 21 contains samples of language in standard PBM contracts with retail pharmacies. Typical relevant contract language in a contract with a retailer pharmacy states reimbursement is "AWP less 13%."

[39] *See* CVH 000028-31, attached as Exhibit 22.

[40] BMS AWP 000125508-09, attached as Exhibit 23.

[41] BMS AWP 000125511-12, *id.*

[42] BMS AWP 000125513, *id.*

[43] BMS AWP 000125514-15, *id.*

the contracts that I have examined, generic reimbursement always references AWP. When a generic version of a drug first becomes available, reimbursement is based on a discount off of AWP, just like brand name drugs. When there are multiple generics on the market, PBMs will reimburse (and charge third-party payors) based on the lesser of AWP less a discount, the usual and customary charge of the pharmacy, or the Maximum Allowable Cost (MAC).[44]

Due to the recordkeeping in the industry we can identify those health plan payments for generic drugs that are expressly based on AWP. For example, I examined the claims data for Harvard Pilgrim Health Care ("HPHC") in this case and we are able to identify how many transactions were based on AWP. [redacted]

The Recordkeeping in the Pharmaceutical Industry Facilitates Computation of AWP-Based Transactions

The last topic I address is the unique nature of the transactional data that allows plaintiffs and the Court to isolate AWP transactions, which will be useful in the claims or damage process.

In this industry, it is possible to identify which third-party payor transactions were based on AWP. PBMs and third-party payors process a huge number of pharmacy and medical claims and so they must rely on electronic claims adjudication and payment algorithms to determine allowable reimbursement for each one. These algorithms essentially match each claim with the appropriate benefit and reimbursement contract information and leave us with a record of the exact amount paid and, in many cases, the formula used to calculate the allowed amount. For example, I examined the claims data for Harvard Pilgrim Health Care in this case and found a field that listed whether the claim was paid based on AWP or some other benchmark (97% of all of HPHCs pharmacy claims were paid based on AWP). A similar exercise can be done on the databases of other third-party payors so that AWP transactions can be isolated.

Summary of the Importance of AWP

AWP is the reference point for pharmaceutical reimbursement rates. All or substantially all reimbursement rates for pharmaceuticals purchased under public sector and private drug benefit insurance plans are negotiated based upon AWP. This is true for physician-administered drugs and for self-administered drugs. More importantly in this case, the PBM/payor class is defined as based on contracts that use AWP. By definition, as well as by actual way in which the industry works, AWP is the glue that binds these class members together.[45]

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[44] To stabilize the cost variance of different generic products of the same compound, pharmacy benefit administrators calculate a maximum allowable cost ("MAC") based upon the listed average wholesale prices of competing generic drug manufacturers.

[45] I understand that the Court has been buried in paper related to this motion. As a final exhibit, I attach a short primer, navigating the Pharmacy Benefits Marketplace, California HealthCare Foundation,

January 2003. Although I don't subscribe to each point in the paper, it does provide an excellent overview of the industry and the various players (attached as Exhibit 24).